Citation:

Lowe MR, Tappe KA, Annunziato RA, Riddell LJ, Coletta MC, Crerand CE, Didie ER, Ochner CN, McKinney S. The effect of training in reduced energy density eating and food self-monitoring accuracy on weight loss maintenance.*Obesity* (Silver Spring). 2008 Sep; 16(9): 2,016-2,023.

PubMed ID: 18483475

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare group weight loss interventions aimed at improving weight loss maintenance on body weight.

Inclusion Criteria:

- Body mass index (BMI) 27kg/m^2 or more
- No history in the past 10 years of eating disorders
- No history of bipolar disorder or a major depressive episode
- Not currently taking any psychotropic medications that impact weight
- Not scoring 26 or higher on the Beck Depression Inventory
- No history of substance abuse or dependence disorder
- Absence of other major psychiatric disorders
- Clearance by a physician.

Exclusion Criteria:

Any disease, condition or use of medication that could be expected to impact weight or near-term life expectancy.

Description of Study Protocol:

Recruitment

Subjects were recruited into the study through a newspaper story by a local columnist, advertisements in local newspapers and through affiliated physicians.

Design

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22-week randomized controlled trial.

Dietary Intake/Dietary Assessment Methodology

Five-day food records.

Blinding Used

- During the weight loss phase of the study, neither the group leaders nor the participants were aware of the group assignments until week seven
- All three groups received identical treatment for the first eight weeks of the study.

Intervention

- *Weight loss phase:* The weight loss phase was eight weeks in length and was based on an Optifast meal replacement supplemented, 1,100 kcal per day diet
- *Weight loss maintenance phase:* The weight maintenance phase was 14 weeks in length and participants gradually replaced meal replacements with regular foods. Subjects were randomly assigned to three groups during this phase:
  - *Cognitive-behavior therapy (control):* Received basic instruction about nutrition, and behavioral and lifestyle modifications
  - *Enhanced Food Monitoring Accuracy (EFMA):* Received additional lessons to enhance skills for accurate food reporting. Participants also practiced food monitoring daily
  - *Reduced Energy Density Eating (REDE):* Subjects were instructed on a reduced energy density diet.

Statistical Analysis

- One-way ANOVAs and chi-square analyses were used to evaluated group differences at baseline
- Attrition rates were analyzed using chi-square analyses
- Changes during the weight loss phase for the entire sample were evaluated using paired T-tests
- All analyses of outcomes reflecting change in weight or other measures over the course of the study were conducted using mixed model repeated measures ANOVAs, with time as the within-subjects factor and intervention group as the between-subjects factor. Post-hoc analyses testing for specific group differences were conducted using Tukey's test
- For all outcome measures, analyses were done with completers and "intent to treat" data using the baseline carried forward imputation.

Data Collection Summary:

Timing of Measurements

Assessments were conducted at baseline, post-weight loss (eight weeks), post-intervention (22 weeks) and at six- and 18-month follow-ups.

Dependent Variables

- Body weight was measured on a digital scale to the nearest 0.1 lb
- Lipid analyses were done fasting to measure total cholesterol, triglycerides, high-density

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lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol.

Independent Variables

- Intervention group
- Dietary intake was measured using five-day food records.

Description of Actual Data Sample:

- *Initial N:* N=103
  - N=35 in the Control group
  - N=35 in the EFMA group
  - N=33 in the REDE group
- *Attrition (final N):* Attrition rate was 9% at week nine, 22% post-intervention, 31% at six months and 40% at 18 months
- *Age:* 43.9±10.5 years
- *Ethnicity:* 61.2% white, 35.9% African American and 2.9% Asian
- *Anthropometrics:* At baseline, there were no statistically significant differences between groups in weight, height or BMI. Mean BMI = 32kg/m^2
- *Location:* United States.

Summary of Results:

Weight Loss

- At week eight, participants had lost a mean of 7.6±2.6kg ($P<0.001$), or about 9% of their initial body weight
- There were no differences in weight loss between groups, which was unlikely as they were all following the same diet intervention for the first eight weeks.

Blood Lipids

All measures of blood lipid levels decreased significantly during the weight loss phase, and then gradually returned toward baseline during the weight maintenance phase ($P<0.001$).

Energy Density

Participants in the REDE group significantly decreased their ED from baseline to week 22 more than the other two groups ($P<0.005$). These results were the same when ED was calculated using food only, as well as with foods and beverages.

Self-Reported Calorie Intake

- There was a statistically significant decrease in calorie intake over the weight loss and weight maintenance phases, but not during the rest of the study ($P<0.001$)
- For all subjects combined, there was no significant correlation between the ratio of reported calories eaten per day divided by current body weight (an assessment of reporting accuracy) and better weight control
- For the EFMA and control groups, there was a significant correlation between the ratio of reported calories eaten per day divided by current body weight (an assessment of reporting accuracy) and better weight control ($P<0.05$), but not for REDE subjects.

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Author Conclusion:

No incrememental weight maintenance benefit was seen in any of the intervention groups tested in this study.

Reviewer Comments:

- *This study had a relatively high attrition rate that contributed to reduced power overall. Attrition was particularly high among African-American and lower-educated participants*
- *Adjustments were not made for potentially confounding factors*
- *Physical activity was not addressed, measured or controlled for in this study*
- *A power analysis was not conducted to determine whether the study was adequately powered to detect differences.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes

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2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes

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5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	No
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	No
6.6.	Were extra or unplanned treatments described?	No
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	No
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	No
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes

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8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes

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